
A GUIDE TO BEST PRACTICES

FOR THE FEDERAL 340B PROGRAM

A collaborative effort of

Commonwealth Medicine, UMass Medical School

Massachusetts League of Community Health Centers

Office of Clinical Affairs, MassHealth



340B BEST PRACTICES WORKGROUP

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INTRODUCTION

This guide attempts to meet the goal of helping community health centers (CHCs) achieve a standard of quality care in the provision of 340B pharmacy services to their patients and efficiency in their management of the 340B pharmacy program. The information provided is intended to act as a tool to make it easier for CHCs to successfully participate in the 340B program.

The development of this guide is the result of the collaboration and participation of the members of the Best Practices Workgroup, a multi-disciplinary team made up of representatives from Massachusetts community health centers, the state Office of Medicaid, the University of Massachusetts Medical School, and the Massachusetts League of Community Health Centers. The guide recommends best practices for CHCs participating in the 340B drug-purchasing program (340B). Unless otherwise noted, the best practices are intended as recommendations, not mandates.

The Best Practices Workgroup endorses this guide and encourages CHCs to adapt the recommendations contained in this document. MassHealth encourages CHCs to use the best practices for a year. The Workgroup will then evaluate their effectiveness, review and edit the practices, and update them as appropriate.

This information is intended as a general guide for CHCs that wish to have access to 340B drugs for their patients, and is not intended nor should be construed in any way as legal advice.

BACKGROUND OF THE 340B PROGRAM

The 340B program was created by the enactment of Public Law 102-585, the Veterans Health Care Act of 1992, which is codified as Section 340B of the Public Health Service Act. The program is administered by the federal Office of Pharmacy Affairs (OPA), which falls under the Health Resources and Services Administration (HRSA).

The program was established to help specific safety-net programs reduce their pharmaceutical expenses. The program enables participants to purchase medications at significant discounts. The result of these lower prices is, on average, lower than Medicaid pricing. This program can help CHCs provide low-cost medications to their patients in the community.

Drugs purchased under 340B are exempt from the Medicaid best-price agreements, established by 42 USC 1396 R-8 which established the Medicaid rebate program. This exemption allows eligible safety-net entities to negotiate and purchase drugs at rates at or below the Medicaid ceiling price.

A small number of entities qualify for the 340B program. These include:

- federally funded 330 CHCs;
- federally qualified “look-alike” health centers;
- disproportionate share hospitals; and
- certain federally funded specialty disease programs (such as those related to HIV and hemophilia).

This guide is designed primarily for health centers. However, some of the information may also be helpful to other entities interested in pursuing participation in a 340B pharmacy arrangement. For a full list of entities eligible for 340B, see www.bphc.hrsa.gov/opa/grantcon1.htm.

I. GETTING STARTED

I Certification and Enrollment in the 340B Program

In general, federally funded 330 health centers and “look-alike” federally qualified health centers (FQHCs) are eligible to participate in the 340B program. If you are planning to participate in the program you:

- must notify the OPA; and
- must register to become certified by completing the appropriate registration form.

Once registered, participation can begin at the start of the following quarter. Both the registration form and directions can be found at www.bphc.hrsa.gov/opa. Click on “Legal Resources.” Click on “340B Program Registration Form for Covered Entities.”

For a CHC to receive 340B prices for medications, the following three factors must be in place.

- The CHC must be enrolled in the federal 340B program.
- The individual receiving a prescription must be a patient of the CHC. An individual will not be considered a “patient” of the entity for purposes of 340B if the only health-care service received by the individual from the health center is the dispensing of a drug.
See www.hrsa.gov/odpp/atdef.htm.
- The prescribing physician must be an employee by or in contract with the CHC.
See www.bphc.hrsa.gov/opa/patdef.htm.

2 Financial Analysis and Business Planning

There are many facets of this program that are unique when compared to the operation of a standard retail pharmacy. As with any new service, participation in the 340B program should be viewed as a new business line that requires advanced planning and analysis. Depending on the resources available to the CHC, this can be accomplished by an in-house financial team or contracted out to a third party specializing in 340B pharmacy start-ups. The Best Practices Workgroup recommends that careful consideration be paid to the knowledge and skills of the internal team, as well as the accessibility of available information related to 340B pharmacy services. The same is true when evaluating a third party. The Workgroup recommends considering those who have experience specifically in working with 340B entities or pharmacy arrangements.

3 Owned-and-Operated or Contract Pharmacy

The CHC may choose to have its own internally operated on-site pharmacy, contract with an organization to run an on-site pharmacy, or contract with an established, local pharmacy to act as the center’s 340B pharmacy. There are different licensing rules, regulatory requirements, and operational considerations, described later in this guide, depending on which option is chosen.

There are many issues that should be reviewed to determine which option is best for each CHC.

Contracted Pharmacy Arrangement

Creating a contractual relationship with a local pharmacy will be attractive to many CHCs primarily because the start-up costs may be minimal. This option may eliminate the need for infrastructure improvement or build-out costs, including the need to hire a pharmacist. In addition, this method may require less support staffing and oversight.

However, the center may still encounter significant expense when purchasing the initial drug stock for their patients. (There are ways to limit this expense. This is discussed in sections “Contracting with Drug Wholesalers” on page 6, and “Selecting a Virtual or Physical 340B Inventory” on page 16.) Services performed by the pharmacy are usually reimbursed at an agreed-upon dispensing fee paid per prescription by the CHC to the pharmacy. A model contract illustrating the obligations of both parties can be found at www.bphc.hrsa.gov/opa/contract.htm and in Appendix A of this guide.

Note: Some of the language in the model contract is required to be in the contracted pharmacy agreement, such as the language that addresses the “bill to - ship to” arrangement. In addition, some recommended expectations are discussed in the section entitled “What a Community Health Center Should Expect from a Pharmacy” on page 5.

Even if a CHC determines that a contractual relationship best meets its' needs, the staff must keep current with pharmacy business as it relates to the center. Some CHCs have hired a pharmacist on staff (or more than one CHC may share a pharmacist) to assist with clinical and operational matters, regardless of the contract pharmacy arrangement. At a minimum, there should be a primary contact person at the center capable of reviewing and understanding both financial and utilization reports that describe the activities of the pharmacy and the impact of the contractual arrangement on both the CHC and the patients being served. The CHC is always responsible to ensure that both parties meet all state and federal regulatory and statutory requirements.

If a center chooses to establish a contractual arrangement with an existing pharmacy, complete the "Contracted Pharmacy Services Self-Certification Form for the 340B Program" and submit it to the Office of Pharmacy Affairs (OPA). The form can be found at www.bphc.hrsa.gov/opa. Click on "Legal Resources." Click on "Contracted Pharmacy Services Self-Certification Form."

Owned-and-Operated CHC Pharmacy

Many CHCs prefer to own and operate their own pharmacy to ensure access of services to their patients (through direct hiring of staff or contracting with a pharmacy management company).

This option requires that a CHC have or obtain space within or near their center in which to operate a pharmacy. In addition, this option requires that the CHC hire an experienced pharmacist or pharmacy manager to assist in establishing the pharmacy and creating the business plan for the pharmacy's ongoing operation.

The ongoing costs of staffing and operating a pharmacy, as well as the resources and space available to a CHC, will play a significant role in determining which option is best for the center.

4 Impact of 330 Grant Requirements

Community health centers that receive federal funding under Sec. 330 of the Public Health Act and add a 340B prescription-drug program for health center patients must address the following two issues.

Scope of Project

The Scope of Project document addresses five core areas: services, sites, providers, target populations, and service areas. Adherence is an important component of the federal funding requirements (see Bureau of Primary Health Care Policy Information Notice (PIN) 2002-07). It impacts a number of health center functions (such as, malpractice insurance under the Federal Torts Act) and also defines eligibility for certain non-federal programs (such as the Pfizer "Share the Care" program.)

Some centers ask whether a change request to the Scope of Project is necessary for the addition of 340B pharmacy services. Preparation of a request for change requires considerable time and effort, especially since it must be done separately from the annual grant application. In addition, the request may trigger additional federal scrutiny and questions. While each center must make its own determination, there is considerable advantage to filing a change request and potential exposure from a failure to file. The Best Practices Workgroup recommends that the CHC complete a change request form when adding 340B pharmacy services.

Mandate to Deliver Service Regardless of One's Ability to Pay

In general, health centers that receive 330 funding accept an obligation to provide services to every patient seeking care, regardless of ability to pay. However, the extent to which 330-funded centers must provide prescription drugs to patients regardless of their ability to pay does not seem to be clearly articulated in federal law or regulation. The decision on the application of this principle to prescription drugs and the 340B program remains a decision for the center's management and Board of Directors. The following factors need to be considered in making this decision.

- CHCs must consider how implementation of the 340B program would be financed and whether it would obligate them to provide free medications to patients. This obligation may be tempered by other expectations placed on the CHCs.

- The centers have a responsibility to provide sound fiscal management. Providing any services beyond the center's ability to ensure adequate financing could be irresponsible and contrary to the federal operating expectations that centers agree to follow when they receive grant funding.
- Additionally, once a CHC implements a payment policy that may include a sliding fee scale, for this or any other service, it may not be applied in a discriminatory manner. This means that a CHC cannot make an exception for one person and not others falling within the same income bracket. The CHC could be at risk of triggering a discrimination lawsuit if such practices were discovered.

5 State 340B Payment Policies

Medicaid Participation (“Carve In”)

According to federal law, eligible entities can choose whether or not to serve state Medicaid program (MassHealth) members through 340B pricing. However, if they decide to serve Medicaid members with drugs purchased under 340B prices, they may charge only the acquisition price for the drug plus a reasonable dispensing fee. This process is known as the Medicaid “carve-in” and is currently at the discretion of the CHC. Centers may also choose not to dispense drugs to Medicaid members at all or they may dispense drugs to them through the purchase of a separate non-340B inventory billing by the standard state-approved (non-340B) method. Federal law forbids providers from purchasing drugs at 340B prices and charging the state Medicaid program something other than the state-approved 340B rate (acquisition price of the drug and a dispensing fee approved by the state).

MassHealth can benefit from 340B pricing because 340B prices can be lower than the current prices Medicaid pays for the drug after the Medicaid rebate. Lower drug prices translate into providing services to the widest population possible and helps insulate members from potential service cuts due to strapped state budgets. Therefore, Massachusetts would like to increase the number of health centers participating in the 340B program and to increase the number of health center pharmacies that include 340B purchased drugs in their inventory for MassHealth members. In addition, the centers benefit by having this revenue stream where there might otherwise be none.

MassHealth has developed incentives for CHC participation in 340B and the Medicaid “carve-in” policy for MassHealth members. MassHealth pays CHCs actual acquisition costs plus a 340B-entity dispensing fee, an enhanced fee paid to the 340B entity, for each prescription that it fills with drugs obtained at 340B prices. (For the current amount of the 340B-entity dispensing fee, check the Division of Health Care Finance and Policy (DHCFP) regulations that describe all MassHealth pharmacy rates at www.mass.gov/dhcfp.)

Educational services, planning, and start-up technical assistance are available to CHCs through the 340B Project Team. The team has access to resources from the MassHealth Office of Clinical Affairs, the Massachusetts League of Community Health Centers, and the University of Massachusetts Medical School.

Finally, the state, through the Division of Health Care Finance and Policy, awarded nearly \$1.4 million in grant funding in fiscal year 2004 to help with planning and start-up costs. It is currently unknown if a similar grant program will be offered in fiscal year 2005.

To comply with federal law, health centers that “carve-in” Medicaid should alert MassHealth in advance to avoid MassHealth claiming a “duplicate discount.” A duplicate discount would occur if a drug is purchased under 340B and MassHealth submits a rebate for the same claim. To ensure that MassHealth does not claim rebates for 340B drugs, contact the MassHealth pharmacy program to inform them of your center's participation in the 340B program. (See Appendix B: Contact Information for Consultation.)

Payment for Services to Qualified Uninsured Individuals (former Uncompensated Care Pool)

To see the most current regulations about Uncompensated Care Trust Fund payment policy, see 114.6 CMR 11.00: Administration of the Uncompensated Care Pool, on the DHCFP Web site at www.mass.gov/dhcfp.

II. ELEMENTS OF BEST PRACTICES: BUSINESS PROCESSES

I Developing a Relationship with a Pharmacy

One of the most important aspects of operating a successful 340B program is for the CHC to have a good relationship with the pharmacy and its staff. This is true for both owned-and-operated as well as contract-pharmacy arrangements.

2 What a Community Health Center Should Expect from a Pharmacy

The following points should be considered when building a successful relationship with the pharmacy:

- a location close to the health center;
- hours of operation that are convenient to the patients of the health center;
- employees that can communicate in the language of the center's patients and the ability to distribute drug information in these languages;
- sufficient inventory of 340B-purchased contract drugs on the formulary of the health center to meet the needs of the center's patients;
- sufficient supply of over-the-counter (OTC) drugs and medical supplies to meet the needs of the center's patients and the ability to order special items on request;
- ability to participate in the various insurance plans of the patient population;
- adherence to the guidelines of any patient education pertaining to drug therapy that the health center deems necessary;
- encouragement of any cost-containment issues with which the health center is involved;
- consistent service policies for all health center patients regarding hours of operation, prescription wait time, and any other customer service issues;
- understanding of 340B-pricing contracts;
- ability to monitor changes in contract prices of medications and notify the health center as appropriate;
- agreement with the health center that the pharmacy will meet all of the requirements of Section 602 of the Veterans Health Care Act of 1992 and Section 340B of the Public Health Service Act. These include:
 - ensuring that there is no diversion of drugs bought by the health center at the 340B discount to other than health center patients;
 - working with Medicaid to ensure that there is no opportunity for potential duplicate discount/rebate; and
 - having the ability to keep prescription records/profiles and perform a complete drug utilization reviews on drugs used in any sample or patient assistance programs for indigent patients with whom the health center participates;
- ability to generate reports requested by the health center in a timely fashion;
- realization that the pharmacy cannot act alone when questions concerning the prescription arise. They must work with the prescriber whenever there are questions involving the prescription. This includes, but is not limited to, calling the prescriber when:
 - there is incomplete or inaccurate information on a prescription;
 - a prescription is written for a non-preferred drug of the patient's insurer. The prescriber may change the prescription or need assistance with prior authorization process for a non-preferred drug; and
 - a prescription is written for a drug not on the health center's formulary;
- meeting of pharmacy and CHC management on a regular basis to ensure continuity of care and feedback on the program as it relates to the center and the 340B program;
- participation in the health center's Pharmacy & Therapeutics (P&T) Committee, and assistance with formulary development, maintenance, and provider education about formulary issues and the 340B program. The pharmacy should perform technical activities such as:
 - dispensing;
 - record keeping;
 - drug utilization review;
 - formulary development;

- formulary maintenance;
- patient profile;
- counseling to patients and providers; and
- managing the health center's inventory; and
- willingness to work with community health centers or other community agencies or providers, uninsured or underserved populations, and people from different cultures.

3 Top 10 Ideas on How CHCs Can Work with Their Contracted Pharmacy

1. Formally meet to discuss and ensure alignment of the goals and needs of each party.
2. Have a person readily available for the pharmacy to contact with any questions.
3. Put in place systems to ensure open communication.
4. Inform the pharmacy of any formulary or policy changes, before the effective date of change.
5. Seek input from the pharmacy about any formulary or policy changes.
6. Get to know the staff/bench pharmacists. They are key members to the program's success!
7. Meet regularly (at least quarterly) to discuss partnership. Be open and honest about what is or is not working for either side.
8. Educate all prescribers about what is on the formulary to minimize situations at the pharmacy regarding a non-covered medication.
9. Educate patients about rules of the program (such as vacation or lost prescription refills).
10. Use electronic means, rather than having a nurse call in the prescription, to manage the pharmacy workflow and reduce errors.

4 Contracting with Drug Wholesalers

Selecting a Drug Wholesaler

One of the first tasks that a pharmacy will have to deal with is to find a source from which to purchase drugs. Today a pharmacy buys its drugs mainly from one wholesaler and picking that wholesaler is an important decision that cannot be based on price alone. The CHC may often use the same wholesaler to purchase medications and medical supplies for use throughout the health center. Some pharmacies also like to have a secondary wholesaler as a backup to their primary one in case of emergency.

When starting a 340B pharmacy in Massachusetts, select a pharmacy that is willing and able to handle the added responsibility of 340B requirements including contracting with a 340B wholesaler. In Massachusetts, this means using one of three wholesalers: AmeriSource-Bergen, Cardinal Health, or McKesson. See Appendix C for a list of contacts for these wholesalers.

Factors in Deciding Which Wholesaler to Select

A. Frequency of Deliveries

Most, if not all, wholesalers will deliver to individual pharmacies once per day on Monday through Friday. A store receiving one delivery a week may pay a lower price than a pharmacy receiving five deliveries a week (if they are each purchasing the same volume). However, this is not a recommended way to lower costs. Instead, consider receiving a daily delivery.

B. Cost of Drugs

No matter what a pharmacy is told by a particular wholesaler, there will not be much difference among wholesalers as 340B prices should be consistent. Wholesalers make their profit by adding an "up-charge" to the standard 340B price. This up-charge, usually a fraction of a percent, is determined by the following:

- total purchases. A pharmacy buying \$100,000 worth of drugs per month will pay a lower up-charge than one buying \$20,000 worth; and
- frequency of payment. A pharmacy that pays for its purchases weekly will pay a lower rate than one paying monthly. Wholesalers will often assign late fees to pharmacies not current with their payments. The norm for payments is twice a month. Payments fall due 10 days after the last day of the payment cycle. For example, payment for orders received between days 1-16 of the month would be expected by the 25th day. Payment for orders received between days 17-31 would be due on the 10th of the next month.

Remember that these up-charge differences will amount to only fractions of a percent. For a pharmacy purchasing \$100,000 worth of drugs per month (a high volume), a difference of .25% would mean a savings of \$250.00 and there will be a negligible difference in cost between these three wholesalers.

C. Initial Drug Purchase

The initial inventory needed to start up a pharmacy can be quite expensive (\$50,000 is not considered an excessive figure). Most wholesalers will give extended payment terms for this opening order requiring three equal payments over 90 days. Depending on the wholesaler's desire to do business with you, you may even be able to negotiate for more than 90 days.

If you are starting a contract pharmacy arrangement, consider using a virtual inventory that requires no initial start-up stock. (See Appendix E: Ideas on Inventory Control and Reporting.)

D. Ease of Ordering

Ordering is usually done in one of two ways.

- The most common way to order is to use your pharmacy management system as a means to maintain a perpetual inventory. The pharmacy will keep an accurate inventory of every item in the pharmacy and set up minimum stocking levels for each item. When a prescription is filled, the inventory is adjusted to the new quantity in stock. When the inventory drops below a predetermined reorder level, the system will automatically place an order. Contract pharmacies need to remember to use caution to ensure that their 340B inventory is tracked separately.
- As an alternative, the wholesaler may supply the software to the pharmacy. This allows the ordering of medications by name or some other agreed-upon method and can provide up-to-the-minute price and drug availability. However, using wholesaler-supplied software is sometimes more time consuming as a primary ordering system. Drug prices change frequently, sometimes daily. Consider selecting a wholesaler that will assist you in receiving management reports that will facilitate the center getting the best prices for the drugs and managing the formulary.

E. Customer Service

When considering a wholesaler, customer service provided to the pharmacy may be more important than price alone. The pharmacy management should include the following factors in their decision-making process.

- How easy is it to return an unwanted item? Is there a “restocking fee” for returned items or will you receive full credit?
- How often will representatives visit?
- How is a recall handled?
- How easy is it to get assistance from an 800 number?
- How frequent are “mispicks” (ordering a particular item but receiving a different item in its place)?
- Does the wholesaler maintain an adequate inventory to avoid out-of-stock issues?
- Is the wholesaler willing to send updates of drug price changes when they occur or on a frequent basis?

F. Other Fees

The wholesaler may have other fees in addition to the cost of drugs (such as a monthly charge for the use of its software, usually under \$200).

5 Policy and Procedure Manual

For the Owned-and-Operated Pharmacy

It is imperative that every in-house 340B pharmacy maintain an up-to-date policy and procedure manual that defines its practice. Policies and procedures should comply with:

- federal and state pharmacy laws, including HIPAA compliance;
- rules and regulations stipulated by the Board of Pharmacy;
- all licenses and certifications held by the pharmacy and the health center; and
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards and the rules and regulations established by the Health Care Quality Division and the Drug Control Program within the Department of Public Health.

The Policy and Procedure manual should contain:

- an organizational chart depicting the structure of the pharmacy;
- a job description section that describes the functions and responsibilities of pharmacists, pharmacy technicians, and other supporting staff;
- a description of:
 - recordkeeping requirements for controlled II-IV substances;
 - a process to handle prescriptions that are electronically transmitted;
 - a process to handle prescriptions that are transferred out of the pharmacy;
 - the definition of eligible users and the steps necessary to verify their eligibility to avoid dispensing 340B medications to non-340B eligible patients;
 - the workflow of the pharmacy;
 - the operation of an automated dispensing machine (if applicable);
 - the practice of medication compounding;
 - the necessary licenses maintained by the pharmacy;
 - the disaster plan in the event of power failure or malfunction of pharmacy computer system that addresses critical functions;
 - a process to handle and report adverse drug events;
 - the maintenance of pharmacy inventory (340B vs. non-340B drugs);
 - the monthly reports that the contracted pharmacy generates and sends to the health center; and
 - the policy and procedure when patients fail to pick up medications (both patients and prescribing clinicians should be contacted, as appropriate, and inventory should be credited to the correct inventory).
- interface and operation of the Pharmacy & Therapeutics (P&T) Committee and the management of the drug formulary (if applicable);
- prohibited use of dangerous abbreviations, as established in the National Patient Safety Goals of JCAHO standards (if JCAHO certified); and
- a policy that mandates the use of two unique identifiers to verify patients' identity to prevent dispensing wrong medications to patients, as established in the National Patient Safety Goals of JCAHO standards (if JCAHO certified).

For the Contract Pharmacy

A health center contracting with a retail pharmacy should review and may adopt the policies and procedures established by that pharmacy, but must ensure that the following additions are made:

- policy and procedures that address how the CHC and pharmacy will interface to manage the 340B program using these suggested best practices;
- a definition of eligible 340B patients and the steps necessary to verify eligibility to prevent dispensing 340B medications to non-340B eligible patients;
- a system of pharmacy inventory maintenance for the CHC (340B vs. non-340B drugs); and
- the frequency and type of monthly reports generated by the pharmacy for the health center.

6 Licensing of Pharmacy to Participate in the MassHealth 340B Program

Owned-and-Operated Pharmacies

A health center with an on-site pharmacy is required to follow the steps listed in the following table to establishing pharmacy licensure for a new pharmacy.

Steps for starting a new 340B pharmacy

The following assumes that the CHC has clinical license.

Steps	Agency contact and phone number
Office of Pharmacy Affairs (OPA)	
1. Become 340B certified	
1A Make sure your organization is federally qualified.	Pharmacy Services Support Center 1-800-628-6297 http://bphc.hrsa.gov/opa
1B Receive certification to participate in 340B program.	
1C Fill out application from OPA Web site and submit it (or notify them that you are “carving-in” Medicaid).	
Department of Public Health (DPH)	
2. Get appropriate pharmacy registration from DPH	
2A Pursue architectural plan approval from DPH/Division of Health Care Quality (DHCQ) to add pharmacy service to existing license-download forms from Web site.	Daniel Gent, Plan Review DHP/DHCQ 10 West St., Boston, MA 02111 617-753-8116 www.mass.gov/dph/dhcq/plan.htm
i) Obtain approval to construct or make any alterations to existing space-plan. Approval may take 90-120 days-if design needs change, can take another 30-45 days.	
ii) Get inspection certificate from MA Department of Public Safety-required before licensure.	Dept. of Public Safety 617-727-3200
iii) Contact local building inspector to meet local requirements.	
iv) Request a clinic survey from DPH/DHCQ. Complete form and attachments at least two months before projected date of occupancy. After application is reviewed for adequacy, you will be contacted by DPH/DHCQ to arrange an on-site survey.	David Brown DPH/DHCQ 10 West Street, Boston, MA 02111 617-753-8115
2B Apply to DPH Drug Control Program (DCP), within the Division of Food and Drugs, to get MA Controlled Substance Registration (MCSR)-download forms from Web site.	Patricia Calvagna-Lusk, Program Coordinator 617-983-6700 www.mass.gov/dph/dcp/dcpmcsr.htm
OR	
2B If you have an MCSR, send an amendment letter to DCP to change the scope of your practice. An amendment letter is not needed when a contracted retail pharmacy dispenses to CHC patients under their CRS and DEA numbers.	
2C After architectural plan is approved, apply for a federal DEA number. Note that your MCSR is pending-federal DEA number will be approved once you receive your MCSR.	Barbara Menhart 15 New Sudbury Court, Boston, MA 02203 617-272-5174
2D Apply to Board of Pharmacy (DPH) for a Controlled Substance Registration (CSR). Note that your MSCR is pending-CSR and DEA number will be approved once you receive your MCSR.	Lau Kwan 239 Causeway Street, Boston, MA 02114 617-727-0085
MassHealth	
3. Enroll in MassHealth 340B Program	Nancy Schiff Pharmacy Unit 617-210-5659
3A Meet requirements for pharmacy provider (license, DEA number).	
3B Get application and checklist from Provider Enrollment and Credentialing.	Provider Enrollment and Credentialing P.O. Box 9101, Somerville, MA 02145 617-576-4424 /1-800-322-2909 703-917-4933 (fax) maproviderupdates@unisys.com
3C Return completed application and checklist to Provider Enrollment and Credentialing.	

For the Contract Pharmacy

Health centers using the contract pharmacy arrangement for their 340B program use the following procedure to participate in the MassHealth Program.

- The qualifying 340B entity must contract with a licensed pharmacy to order and dispense drugs for the health center's patients. The pharmacy must be a MassHealth provider.
- The pharmacy orders the drugs using their pharmacy license and DEA registration.
- The wholesaler sends the drugs directly to the licensed pharmacy and bills the CHC.
- The pharmacy is required to keep the 340B drugs as a separate inventory, either virtual or actual, based on DPH/DEA requirements. The pharmacy must also be able to provide records tracking 340B utilization separately from the pharmacy's non- 340B business.
- To enroll in the MassHealth 340B program, the CHC must complete a checklist for 340B participation from Provider Enrollment. (See 3B and 3C on page 9.)

For more information see Appendix B: Contact Information for Consultation.

7 Increasing the Number of Patients that Use Your 340B Pharmacy

An essential facet to a successful 340B pharmacy is to maximize the number of health-center patients who use the 340B pharmacy to fill their prescriptions, referred to in this document as “capture rate.” Attracting a good mix of patients with different payment sources is important to the financial viability of the pharmacy. In addition, the use of the 340B pharmacy will allow professionals who prescribe to patients to better track adherence and be alerted if a patient has concerns or special needs about their medication. As a result, all centers should aim to maximize the capture rate for their patient population.

CHC Administrators

Each CHC should hire a pharmacist to assume the pharmacy management role or, if it is a contractual arrangement, a pharmacy manager who will oversee the pharmacy relationship. An important aspect of this role is to maximize the capture rate of the 340B pharmacy. The ideal candidate should have experience in a retail pharmacy where customer-service principles are stressed. A pharmacy should ensure that it has the drugs in stock to meet the members' needs to promote higher capture and patient-satisfaction rates.

The Workgroup recommends that CHC administrators have systems in place to help ensure that members do not lose their insurance coverage if at all possible. Ask MassHealth members if redetermination forms have been completed and submitted on time. If a patient is a free-care member, help them determine if they are eligible for MassHealth and submit a MassHealth application. Educate members about the importance of maintaining continuous health-care coverage and the role that health insurance plays in the continuity of care.

Have the pharmacy in a location that is convenient to your patients and where they can see it. Try to have an in-house pharmacy near the main exit of your building. When using a contract pharmacy, it should be located as close to the health center as possible or close to where the patients live.

Consider purchasing a computer system that can be configured to allow clinicians access to see if patients are filling their prescriptions, saving both time and money as well as improving clinical outcomes.

Consider having the prescribers write the prescription on a CHC-designated prescription pad or some other special CHC patient designation. This will help the pharmacist distinguish a 340B-eligible prescription from one that is not eligible for the 340B pricing.

Consider having a good selection of over-the-counter (OTC) drugs for health-center patients. OTC drugs may be purchased through the 340B program at significantly discounted prices. Keeping retail costs lower than competitors will not be difficult when purchasing through 340B, as major chain stores usually inflate their retail price on generic OTCs. This can lead to increased profits and patient visits or these savings can be passed on to patients of the health center.

Note: Pharmacies need to have procedures or systems in place that ensure diversion of 340B-priced OTC drugs does not occur.

Pharmacist and Administrators

This section addresses the needs of a CHC-owned-and-operated pharmacy. However, many of these suggestions can be applied to contracted pharmacy arrangements. Before the pharmacy opens, the Workgroup recommends that the health center set up a system to promote a maximum number of patient visits to the pharmacy by informing members about the 340B pharmacy.

The health center administrator, medical director, and pharmacy leadership should educate and create enthusiasm in staff and patients in anticipation of the pharmacy opening.

- Consider displaying posters, in a variety of languages, throughout the health center. Posters that market the clinic's pharmacy to patients can include the following points:
 - It is more convenient to get all health services from one trusted entity.
 - The prescription is easier to fill at the same time that the patients are visiting their doctors.
 - The pharmacy staff speaks the languages that your patients speak.
 - OTC products are available at lower cost.
 - Patients help the CHC and other patients by using the CHC-sponsored pharmacy. This allows the CHC to purchase drugs and supplies at lower prices, freeing up dollars to provide care to individuals with no health-care coverage.
- Publicity could also be generated through the local media.

Medical Director

- Work with the CHC administrator and pharmacy leadership to integrate the 340B program into the day-to-day operations of the CHC.
- Establish an understanding among clinicians on the importance of utilizing the pharmacy.
- Work with the pharmacist to explain the benefits of an in-house pharmacy to all the clinicians on staff. These benefits can include:
 - significantly reduced costs for uninsured patient (especially generics);
 - revenue from the 340B pharmacy can help pay for uninsured patients' medications;
 - ease of use, since patients can receive all health-care services under one roof;
 - adherence reports for clinicians from the pharmacist;
 - patient education about prescriptions;
 - customer service and language assistance; and
 - improved clinical relationship between pharmacy and prescribers.

Pharmacy Director

- Work with the CHC administrator and medical leadership to integrate the 340B program into the day-to-day operations.
- Establish lines of communications with prescribing clinicians at the health center.
- Generate patient compliance reports and establish a procedure to notify clinicians of these results. Clinicians appreciate knowing who is being compliant with their medications. Make this a major selling point of the pharmacy.
- Keep clinicians abreast of changes in prescribing policies for various insurance plans and MassHealth.
- Ensure that clinician-selected/approved items are in stock.
- Have someone on staff that speaks the languages of your patients. For the pharmacy to be successful, this concept cannot be overstated.
- Work with staff to provide good customer service to health-center patients. These efforts will make the pharmacy an attractive option for all patients.

Prescribing Clinicians

- Prescribe drugs that are on the health-center formulary.
- Explain the benefits of the in-house pharmacy to the patients.
- Explain how the 340B program serves as a valuable bridge from samples and Patient Assistance Programs (PAPs).

Patient Education

Various materials for patient education have been developed to help patients understand the benefits of using the CHC 340B pharmacy. Please contact the League of Community Health Centers for examples of Patient Education Materials. (See Appendix B for contact information.)

8 Alternative Programs for Low-Income and Uninsured Patients

Implementation of a 340B pharmacy is a great step in increasing access to low-cost pharmaceuticals for CHC members. However, this program should continue to be just one part of the continuum of possibilities for low-income and uninsured or underinsured patients. Many CHCs already use both Patient Assistance Programs (PAPs) and samples to assist patients in accessing medication. This practice should continue to be equally, if not more, critical after the implementation of a 340B-pharmacy arrangement.

Note: It is good clinical practice to inform patients that, if they are receiving medications under PAPs or sample programs, their medications may change periodically based on availability and program eligibility. Also, if they are eligible to receive health insurance, the coverage they are eligible for could impact their medication regime. CHCs are encouraged to educate the patient who is participating in PAP or sample programs about MassHealth and help them apply for it, if appropriate.

Patient Assistance Programs (PAPs)

42 U.S.C. 1396r-8 requires any manufacturer that participates in the Medicaid Best Price Rebate Program to also have some program that provides free medications to uninsured patients who cannot afford the cost of medications. There are very few federal limitations on how these programs are established or implemented and which patients qualify. However, most major brand-name pharmaceutical companies have some PAPs for their products. Currently, there are over 135 different programs.

Once enrolled, most programs allow patients to re-enroll periodically for an unlimited amount of time. It is not unusual for clinics to dedicate significant staff time and resources to helping patients access and become enrolled in these programs. Some clinics outsource this task to other third-party companies in order to reduce staff time and resources spent on these tasks.

Traditionally these programs have been difficult to navigate and it often takes 6-to-12 weeks for a patient to become enrolled and receive medication. Because of recent pressure, the pharmaceutical companies have been working to make these programs easier to navigate. Several companies and organizations, including Pharmaceutical Research and Manufacturers of America (PhRMA), have created Web-based forms that enable patients to easily enter the drugs that they need and their personal information including income and citizenship. Patients can then complete the application, have it signed by their physician, and mail it in for enrollment. Once enrolled, the medications are sent to the physician's office for the patient to pick up.

In addition, some organizations help providers enroll their patients in these programs, by calling an 800 number or using a Web-based application from the physician's office. Some of these organizations help the patient track the application and work with the PAP to make sure the application is processed and the patient enrolled. Once the patient receives the medication, the organization puts the patient in its database for automatic re-enrollment reminders and/or ticklers for refills. One such organization, MedBank Maryland, has set up a local mail-order pharmacy that sends medications to patients in anticipation of qualification and enrollment in the PAP. This model has also been replicated in Hawaii. Some helpful links for organizations that assist patients or providers in this process are listed below.

- www.helpingpatients.org PhRMA-sponsored program that providers or patients can use to determine eligibility for PAPs as well as potential eligibility for other state- and federal-sponsored coverage or assistance programs.
- www.rxassist.org similar to the PhRMA site, provides the database searching tool for the PAPs available to providers or patients.
- www.indicare.com: providers may contract with IndiCare to complete the process for their patients.

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- www.massmedline.com MassMedLine, sponsored by the Mass. College of Pharmacy and Office of Elder Affairs, serves as an information portal for patients about the various free-drug assistance programs available to low-income people in the Commonwealth of Massachusetts. Although forms are available, they do not directly assist patients in applying for programs.

Samples

Using sample medications is one way to provide free medications to patients and keep your free-care formulary costs down. One limiting factor in sample distribution can be the supply reliability. The majority of drugs sampled are new brand-name medications. A difficult situation can arise if there are competing medications in the same class and the samples are delivered sporadically, forcing the provider to continuously change the patient from one drug to another.

We recommend that you assess your sampling practices and stock. Align sample medications and Patient Assistance Programs (PAPs). For patients who qualify, sample medications that are also included on PAPs can be very helpful in keeping the cost of the formulary down. Since application to these programs can take some time for medication delivery, samples can act as a bridge to PAPs.

- Free samples from the manufacturers exist and the CHC should take advantage of them as a last resort to supply necessary medications to the patient when there is no insurance alternative. Inform the pharmacy when samples are given, so they can perform drug utilization reviews.
- Educate the patient to the reality that free samples are often brand-name drugs and less expensive drugs may be clinically equivalent and mandatory once the patient has insurance or if the supply of samples runs out.

III. ELEMENTS OF BEST PRACTICES: BUSINESS MANAGEMENT OVERSIGHT

This section is designed for CHCs that are operating a 340B-pharmacy arrangement or completing their planning for future implementation of a 340B pharmacy. This section focuses on how a center can organize its staff and resources to understand their roles related to operating a pharmacy program.

Using the “340B Best Practices Guide,” solicit input through collaborating with pharmacists, clinicians, and administrators on practices and procedures that best support a successful 340B-pharmacy operation.

I Management Oversight

One person from the CHC management team should be given the responsibilities of managing and monitoring the 340B program for the health center and the CHC’s 340B pharmacy. This person would ensure that oversight is provided for both the administrative and clinical components. Consider the corporate leadership, the medical leadership, or the pharmacy leadership as a point person to assume this role.

Administrative oversight responsibilities include:

- forming a 340B management team;
- designating a lead person for the 340B management team. The team is responsible for:
 - setting the general direction and policy for the program;
 - coordinating and delegating tasks;
 - complying with state, federal, and 340B-program regulations;
 - maintaining 330 federal grant standards;
 - developing the budget;
 - overseeing day-to-day operations;
 - communicating with health-center members;
 - creating orientation and in-service training programs; and
 - providing feedback to staff on operational and clinical practices for compliance with the 340B best practices and the 340B program.

Clinical oversight responsibilities include:

- participating in a P&T committee (consider participating in the UMass sponsored CHC P&T Committee);
- overseeing utilization of the MassHealth Drug List (MHDL);
- managing and monitoring compliance with CHC formulary;
- establishing a system to manage samples/indigent care programs;
- overseeing prescribing practices;
- developing, monitoring, and maintaining a patient follow-up policy; and
- establishing a system that complies with Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards for medical management for the pharmacy.

The 340B Management Team

The 340B management team implements and maintains an effective program for centers with on-site and contract pharmacy arrangements.

Their purpose is to:

- review formulary compliance;
- address the pharmacy and CHC operational issues and needs;
- address clinical issues/feedback;
- develop policies and procedures and monitor the compliance; and
- strategize means of maximizing the capture rate for pharmacy. (See information in the section “Increasing the Number of Patients that Use Your 340B Pharmacy” on page 10.)

Ideally, the 340B management team will include:

- the 340B program leadership;
- a representative from the P&T Committee;
- a prescriber;
- a practicing bench/dispensing pharmacist;
- the project manager for the health center; and
- the pharmacy leadership and/or the project manager for the pharmacy.

Maintaining the Program

- Have the 340B management team meet as needed in the development of the program and to set up regular, scheduled meetings. The meetings should be at least quarterly, but it is recommended to meet monthly to optimally maintain the program.
- Share this “340B Best Practices Guide” with the team.
- Stress open communication and partnership between the pharmacy and the health center. The CHC should have a contact person at the pharmacy.
- Have a 340B project manager both at the health center and at the pharmacy. If there are multiple sites, there needs to be a key contact at each site.
- Encourage ongoing communication with the center’s prescribing clinicians.
 - Have 340B as a standing agenda item on CHC meetings, both clinical and operational (such as, clinical, urgent care, nursing, financial, dental, and pediatrics).
 - Integrate the 340B program into standard CHC activities.
 - Incorporate the 340B program into staff and patient orientation at all levels.
- Maintain utilization and compliance reports to monitor the program.
- Solicit ongoing feedback on 340B-program operations.
- Have a system of inventory controls in place.

Reporting

Reporting is important for both monitoring daily operations and to ensure that the pharmacy complies with all state and federal laws and regulations governing the 340B-program regulations. When designing a reporting procedure:

- consider what information is necessary in order to manage and maintain the program in the CHC and the pharmacy;
- consider including prescribing clinicians in the decisions on what reports are helpful, how they are designed, and the frequency the reports are produced;
- develop reports that help staff be proactive in anticipating what needs to be done to manage and correct problems;
- develop reports that can be used to educate health center staff or to assist in the management of the 340B program; and
- maintain copies of the reports in accordance with applicable laws and for historical purposes.

Ideally the pharmacy should have the ability to produce the following types of reports:

- utilization review;
 - design reports to enable a review of all pharmacy utilization, including reports about drugs most frequently prescribed and drugs that are most expensive;
- inventory control, including the monitoring of OTC drugs and samples;
- inventory sales;
- formulary compliance by prescribing clinicians;
 - design reports to review drugs dispensed by brand/generic and by drug class and cost to review formulary compliance;
- patient adherence to scripts written/scripts filled; and
- expenses vs. revenue.

For more specific information produced by the pharmacy, see Appendix D: Types of Reports Produced by a Pharmacy.

Inventory Controls

Inventory controls are important in any 340B-pharmacy, but especially for a health center working with a contract pharmacy. The 340B program states that drugs purchased at 340B prices can only be dispensed to patients of the health center. It is illegal to sell these drugs to anyone other than health-center patients. This is known as drug diversion.

For a pharmacy that is owned and operated by the health center, diversion is relatively easy to control because it serves only patients of the center. However, if the health center uses the contract pharmacy model, or if the on-site pharmacy provides drugs to the general public, there must be controls in place to prevent diversion.

Pharmacies can do this by having a separate inventory for the 340B-purchased drugs. Federal law allows this to be accomplished by keeping either a separate physical inventory or a virtual inventory (replenishment system). With a virtual inventory, initial dispensing of 340B medications is completed from the pharmacy's existing stock, but the pharmacist is able to designate each prescription as 340B through the software system, creating a 340B inventory-utilization record. The health center replenishes these drugs at a 340B price and the drugs become part of the 340B inventory purchased by the health center.

In addition, if the health center is purchasing 340B drugs for their MassHealth members, federal law requires that it bill MassHealth at the actual acquisition cost plus the dispensing fee. Actual acquisition cost is the fee that the health center actually paid for the drug, so accurate records need to be kept.

The health center's responsibilities are:

- keeping accurate records of all interactions;
- maintaining a perpetual inventory for the 340B program;
- keeping the integrity of system reports. It is recommended to:
 - print out the order from the previous day;
 - transmit purchase order to wholesaler (share's price);
 - look at inventory (expected invoice vs. actual price);
 - check to see how large the variance is (a 1-1½% variance in price from the wholesaler price and the 340B price is an accepted threshold); and
 - record weekly acquisition price updates into the drug record.

The pharmacy responsibilities are:

- making sure the acquisition price is accurate;
- ensuring that software has the ability to change manufacturers;
- having systems in place for managing and controlling the pharmacy inventory; and
- ensuring appropriate use of 340B-purchased drugs.

Selecting a Virtual or a Physical 340B Inventory

The information provided below is designed to assist health centers in determining the difference between a physical inventory system (two separate actual drugs stocks) and a virtual inventory (the pharmacy uses a software program and audits to track, replenish, and account for prescriptions filled by either the 340B or non-340B patients).

Inventory Type	Pro	Con
Virtual	No up-front cost of drug to the health center	Increased paperwork for pharmacy to maintain Financials harder to understand, e.g., always an outstanding balance of drug due to the pharmacy
Physical	Ease of ordering stock Easier understanding of financials	Health center must pay for initial drug inventory and assumes more of a financial risk

In general, when a virtual inventory method is selected, the brunt of the recordkeeping and financial risk is assumed by the pharmacy. In an actual inventory, the upfront costs and paperwork burden are assumed by the health center. Pharmacies may prefer an actual inventory due to less paperwork.

However, there is also great advantage to virtual inventory.

Virtual inventories are easier to manage if there is a small formulary. However, if a health center wishes to have access to all 340B drugs for its patients, the virtual inventory recordkeeping and maintenance can be quite overwhelming and, currently, there are few software systems available to help.

Keeping an actual physical inventory that is separate for the health center can be a financial burden for the health center up front, as the health center must purchase all the drugs for the initial setup. However, with an actual inventory there is less paperwork involved in maintaining the inventory, but more storage space for medications is necessary.

There are some additional issues that need to be considered when using a virtual inventory. These are:

- having a system in place to manage price changes in a timely manner, as generic prices change frequently;
- ensuring that staff pharmacists have the ability to change the price in the system at the bench;
- consolidating business needs (use the same bottle for both inventories, have CHC order 340B stock to replenish inventory, and tabulate how many in the bottle were used at the old price);
- developing a way to record activity; and
- keeping records of how many drugs are ordered by NDC number (replenishment issue).

Claims Processing

The CHC and the pharmacy should have a system in place to manage, with the wholesaler, price changes, and incorporate these changes in a timely manner in the various reporting systems. The claims system should accurately record the cost of goods, best price, reordering activity, and accurate reporting. The CHC and the pharmacy should establish a reconciliation process.

Billing

The pharmacy would benefit by having software with the capacity for uploading 340B prices rather than having to complete this process manually. Some software will allow for electronic downloads, directly from the wholesaler, for acquisition costs based on NDC number.

How to bill MassHealth:

- MassHealth pays the health center acquisition cost plus a 340B-entity dispensing fee for its 340B purchased drugs. In a contract pharmacy arrangement, the health center is responsible for paying the pharmacy.
- Health centers with an owned-and-operated pharmacy are required to get a MassHealth provider number that must be used to submit claims to the Pharmacy Online Processing System (POPS).
- Health centers contracting with a pharmacy will, as part of their contract, have the pharmacy submit the claims to POPS for their 340B program.

2 Clinical Oversight

Pharmacy & Therapeutics Committee

Each health center is required to have a Pharmacy & Therapeutics (P&T) Committee by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The goal of a P&T committee is to manage drug costs by making decisions regarding the most appropriate drug therapies based on safety, efficacy, and cost.

A statewide P&T Committee is being organized by the University of Massachusetts Medical School (UMMS) Drug Utilization Review (DUR) Program, which will be made up of representatives from CHCs participating in the 340B program. One purpose of the committee is to develop an optional statewide formulary for 340B-purchased drugs. Consider participating in this P&T Committee and/or using the MassHealth Drug List (MHDL) statewide formulary. The MHDL formulary can be adapted to fit your center's needs.

For more information on tasks and resources of this new statewide CHC P&T committee, see Appendix F: Development of Statewide CHC Pharmacy & Therapeutics (P&T) Center.

P&T committees began in hospitals in the early 1960s as an effort to maximize rational drug use through the careful consideration of a product's safety and efficacy. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) mandated their existence in 1965. In the early 1980s, managed care adopted the use of a P&T committee to create drug formularies for the outpatient setting. In these early days, the drug formulary was primarily created to designate preferred drugs based on safety, efficacy, and cost and to obtain discounts or rebates from pharmaceutical manufacturers for these preferred drugs.

Committees that originally were comprised primarily of academicians, primary care physicians, medical directors, and pharmacy directors, now utilize the assistance of numerous specialist physicians and advisory consultants.

The goal of a P&T Committee is to meet the increasing demands of controlling the cost of drugs by making decisions about the most appropriate drug therapies for their members based. The process of evaluating and developing a formulary must take into consideration issues relating to safety, efficacy, pharmacoeconomics, and health outcomes. The committee must evaluate the value of drugs selected through the submission of evidence-based outcome analyses. The focus of formulary deliberations must be concerned with evaluating a drug's system-wide impact on resource utilization (purchasing power) and medical costs (controlling costs).

P&T Committee decisions impact significantly on all health-care stakeholders – providers, patients, purchasers, and manufacturers. Their recommendations may range from approval with no restrictions to rejection.

P&T Committee members must be focused on getting the health system they represent to develop a partnership with physicians and pharmacists to work together for the success of the health system.

Developing a Formulary for Your Health Center

When developing the center's formulary, include drugs that are payable under the MassHealth Drug List without prior authorization (PA). The list is designed to encourage the use of the most clinically appropriate, cost-effective drugs in each class. Develop a system that will allow patients to receive non-formulary medications when medically necessary.

Formulary development will differ greatly depending on who the formulary is meant for and what type of pharmacy arrangement your center chooses. You will need to stock any medications that you have on your formulary, as well as those medications that are covered on formularies of third-party insurers from whom you accept coverage. Inventory adds up fast and can be costly, so careful planning of what you stock compared to what your patient population needs is imperative. In addition, ensuring that you have the needed drugs in stock allows for a higher capture and satisfaction rate of your patients. In considering how to develop a formulary, ask the following question:

- Who is the formulary meant for?
- What about free-care patients?
- Has an attempt been made to streamline health-center prescribing?

Almost all health plans have developed a formulary for medications. If a patient has prescription insurance coverage, the formulary is already determined by the health plan. Unfortunately not all health plans have chosen the same medications, so providers are continuously challenged to figure out which medications are covered by the patient's plan.

Determine your scope of coverage. Defining a scope of coverage facilitates formulary development and management. Defining your scope allows the center to focus on certain diseases and can eliminate coverage of non-medically necessary medications (such as cosmetic or lifestyle medications like certain topical creams and drugs for the treatment of sexual dysfunction). Formatting your formulary according to medical condition helps to organize the covered medications.

Assess your sampling practices and stock for uninsured patients. Align sample medications and PAPs.

Review the formularies of the third parties that you see most often.

- What is your payer mix?
- What do the formularies have in common?

Reviewing the formularies of health plans that the majority of your patients are covered by allows you to see patterns and to streamline your formulary by including the same medications. This step will make it easier for the provider to select a particular medication as one that they are already used to prescribing and one that the pharmacy is likely to have in stock.

In developing a formulary consider:

- having at least one medicine from each class to be covered based on the medicine's efficacy, safety, ease of use, and economic considerations;
- working on one medical condition at a time;
- working on one class at a time, if applicable (for example, review all ACE inhibitors); and
- inviting comments from specialists in your health center.

In choosing which medications are covered on the formulary determine:

- how the selected agent fits in with other formularies;
- if the medication is available as a sample; and
- if the selection of a medication will affect availability of samples.

Document the rationale for medication selection, including any P&T Committee member disclosures (such as, payment as a consultant or speaker for a certain drug).

Develop a system for noncovered drugs by having providers document:

- the reason for variance from the formulary;
- failed attempts of the patient on formulary medications;
- if a drug class that is a patient necessity is not available on formulary; and
- if a similar agent is available as a sample.

3 Staff Training and Orientation About the 340B Program

In order to maintain an effective 340B program and the management of pharmaceuticals, it is important for the CHC and pharmacy to provide initial and ongoing education about the 340B program. Consider:

- having a designated person, such as the staff developer, work in conjunction with the CHC administrator and the medical and pharmacy directors to implement training about the 340B program;
- establishing orientation and ongoing in-service training for CHC and pharmacy staff about the benefits of the program;
- including feedback from P&T, pharmacists, and staff in planning the content of these trainings;
- having the staff developer conduct a survey and collect feedback on the 340B program from members, the pharmacy, and the CHC staff, and share survey results with CHC and pharmacy director;
- creating posters or pamphlets that target patients in exam rooms and waiting areas with information and benefits about the 340B pharmacy program; and
- training staff to acquaint patients about the program and encourage them to get prescriptions filled at the 340B pharmacy.

4 Subject Matter Content for 340B Training Sessions

Staff Developer

- Create a 340B-program overview and orientation.
- Be familiar with current best practices recommendations.

Prescribing Clinicians and Other Clinical Staff

- Familiarize clinicians about the benefits to patients using the CHC's 340B pharmacy so they can inform patients when prescribing medications.
- Familiarize prescribing clinicians and nursing staff with the importance of using the 340B formulary and making their patients aware of the program.
- Acquaint prescribing clinicians with formularies from the different insurers.
- Instruct prescribing clinicians how to access formulary information by:
 - palm pilot;
 - pocket cards;
 - copies in exam room; and
 - shared drive.
- Instruct clinicians about the center's policy on using samples and PAPs.
- Encourage prescribing clinicians to participate in the design and on-going analysis of reports used to monitor patient medication compliance, prescriber formulary compliance, etc.
- Know who on the health-center staff can assist patients to apply for patient assistance programs or, if eligible, MassHealth.

Customer Services

- Inform customer service staff about the 340B program, its benefits, and what they should tell members, including:
 - what 340B program is;
 - who can use it, when, and where; and
 - why it is important to take advantage of the program.
- Create frequently asked questions (FAQs) and share with the members and staff.
- Conduct and collect surveys to get feedback on the 340B program from members.

Enrollment and Financial Staff (social workers, outreach workers, eligibility workers)

- Review Patient Assistance Programs (PAPs) and educate patients about them.

IV. APPENDICES

Appendix A: Model 340B Contract for Pharmacy Arrangement

Appendix B: Contact Information for Consultation

Appendix C: Contact Information for 340B Wholesalers

Appendix D: Types of Reports Produced by a Pharmacy

Appendix E: Ideas on Inventory Control and Reporting

Appendix F: Development of Statewide CHC Pharmacy & Therapeutics (P&T) Center

APPENDIX A: MODEL 340B CONTRACT FOR PHARMACY ARRANGEMENT

Excerpted from Federal Register, August 23, 1996 (Vol. 61, No. 165, page 43555)

(C) Contract Pharmacy Services Revised Final Mechanism

(1) The following is a suggested model agreement format:

- a) The covered entity will purchase the drug and assume responsibility for establishing its price, pursuant to the terms of a PHS grant (if applicable) and any applicable consumer protection laws. A “ship to, bill to” procedure may be used in which the covered entity purchases the drug; the manufacturer bills the entity for the drug that it purchased, but ships the drug directly to the contract pharmacy.
- b) The contractor will provide all pharmacy services (e.g., dispensing, record keeping, drug utilization review, formulary maintenance, patient profile, and counseling). Each covered entity that purchases its covered outpatient drugs has the option of individually contracting for pharmacy services with the pharmacy of its choice. The limitation of one pharmacy contractor per entity does not preclude the selection of a pharmacy contractor with multiple pharmacy sites, as long as only one site is used for the contracted services. [The OPA will be evaluating the feasibility of permitting these covered entities to contract with more than one site and contractor.]
- c) The covered entity health care provider will inform the patient of his or her freedom to choose a pharmacy provider. If the patient does not elect to use the contracted service, the patient may obtain the prescription from the covered entity and then obtain the drug(s) from the pharmacy provider of his or her choice.

When a patient obtains a drug from a retail pharmacy other than the entity contract pharmacy, the manufacturer is not required to offer this drug at 340B pricing.

- d) The contractor may provide the covered entity services, other than pharmacy, at the option of the covered entity (e.g., home care, reimbursement services). Regardless of the services provided by the contractor, access to 340B pricing will always be restricted to only patients of the covered entity.
- e) The contractor and the covered entity will adhere to all Federal, State, and local laws and requirements. Additionally, all PHS grantees will adhere to all rules and regulations established by the grant funding office. Both the covered entity and the contract pharmacy are aware of the potential for civil or criminal penalties if the covered entity and/or the contract pharmacy violate Federal or State law. [The Department reserves the right to take such action as may be appropriate if it determines that such a violation has occurred.]
- f) The contractor will provide the covered entity with reports consistent with customary business practices (e.g., quarterly billing statements, status reports of collections and receiving and dispensing records). See Section 2 of Appendix.
- g) The contractor, with the assistance of the covered entity, will establish and maintain a tracking system suitable to prevent diversion of section 340B discounted drugs to individuals who are not patients of the covered entity. Customary business records may be used for this purpose. The covered entity will establish a process for a periodic random (sample) comparison of its prescribing records with the contractor’s dispensing records to detect potential irregularities. See Section 3 of Appendix.
- h) The covered entity and the contract pharmacy will develop a system to verify patient eligibility. [The Department’s draft guidance defining covered entity “patient” is set forth in an August 3, 1995, Federal Register notice. See 60 FR 39762.] Both parties agree that they will not resell or transfer a drug purchased at section 340B pricing to an individual who is not a patient of the covered entity. See section 340B(a)(5)(B). The covered entity understands that it can be removed from the list of covered entities because of its participation in drug diversion, a 340B(a)(5) prohibition, and no longer be eligible for 340B pricing. See Section 4 of Appendix.
- i) Both parties will not use drugs purchased under section 340B to dispense Medicaid prescriptions, unless the contract pharmacy and the State Medicaid agency have established an arrangement to prevent duplicate discounting.
- j) Both parties understand that they are subject to audits (by the Department and participating manufacturers) of records that directly pertain to the entity’s compliance with the drug resale or transfer prohibition and the prohibition against duplicate Medicaid rebates and 340B discounts. See section 340B(a)(5).

The contractor will assure that all pertinent reimbursement accounts and dispensing records, maintained by the contractor, will be separate from the contractor's own operations and will be accessible to the covered entity, the Department, and the manufacturer in the case of a manufacturer audit.

- k) Upon request, a copy of this contract pharmacy service agreement will be provided to a participating manufacturer which sells covered outpatient drugs to the covered entity. All confidential propriety information may be deleted from the document.

===== *End of 1st excerpt* =====

Excerpted from Federal Register, August 23, 1996 (Vol. 61, No. 165, pages 43555-43556)

In negotiating and executing a contracted pharmacy service agreement pursuant to these guidelines, contractors and covered entities should be aware of and take into consideration the provisions of the Medicare and Medicaid Anti-kickback Statute, 42 U.S.C. 1320a-7b(b). This statute makes it a felony for a person or entity to knowingly and willfully offer, pay, solicit, or receive remuneration with the intent to induce, or in return for the referral of, Medicare or a State health care program business. State health care programs are Medicaid, the Maternal and Child Health Block Grant program, and the Social Services Block Grant program. Apart from the criminal penalties, a person or entity is also subject to exclusion from participation in the Medicare and State health care programs for a knowing and willful violation of the statute pursuant to 42 U.S.C. 1320a-7(b)(7).

The anti-kickback statute is very broad. Prohibited conduct covers not only remuneration intended to induce referrals of patients, but also includes remuneration intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by Medicare or a State health care program. The statute specifically identifies kickbacks, bribes, and rebates as illegal remuneration, but also covers the transferring of anything of value in any form or manner whatsoever. This illegal remuneration may be furnished directly or indirectly, overtly or covertly, in cash or in kind and covers situations where there is no direct payment at all, but merely a discount or other reduction in price of the offering of a free good(s).

Arrangements between contractors and covered entities that could violate the anti-kickback statute would include any situation where the covered entity agrees to refer patients to the contractor in return for the contractor agreeing to undertake or furnish certain activities or services to the covered entity at no charge or at a reduced or below cost charge. These activities or services would include the provision of contracted pharmacy services, home care services, money or grants for staff or service support, or medical equipment or supplies, and the remodeling of the covered entity's premises. For example, if a contractor agreed to furnish covered outpatient drugs in return for the covered entity referring its Medicaid patients to the contractor to have their prescriptions filled, the arrangement would violate the anti-kickback statute. Similarly, if the contractor agreed to provide billing services for the covered entity at no charge in return for the covered entity referring its patients to the contractor for home or durable medical equipment, the statute would be violated.

Pursuant to the authority in 42 U.S.C. 1320a-7b(b)(3), the Secretary of HHS has published regulations setting forth certain exceptions to the anti-kickback statute, commonly referred to as "safe harbors." These regulations are codified at 42 C.F.R.100.952. Each of the safe harbors sets forth various requirements which may be met in order for a person or entity to be immune from prosecution or exclusion for violations of the anti-kickback statute.

===== *End of 2nd excerpt* =====

Two of the safe harbors that may pertain to arrangements between contractors and covered entities involve discounts and personal services or management contracts.

Covered entities that elect to utilize the contracted pharmacy mechanism must submit to the Office of Pharmacy Affairs a self certification that they have signed an agreement with the contracted pharmacy containing the aforementioned provisions.

Revised 1/06/2000

APPENDIX B: CONTACT INFORMATION FOR CONSULTATION

Office of Medicaid (MassHealth):

1. **Nancy Schiff**, Project Manager
617-210-5659, nschiff@ehs.state.ma.us

Areas of consultation:

- contact person at MassHealth for general information about 340B and MassHealth; and
- MassHealth provider number and other operational issues related to MassHealth and 340B.

2. **Vic Vangel**, RPh, Manager of Pharmacy Operations
617-210-5134, vvangel@ehs.state.ma.us

Areas of consultation:

- experience as former director of a community health center 340B pharmacy;
- pharmacy operations at MassHealth;
- clinical issues related to the 340B program;
- pharmacy software and inventory control;
- pharmacy reports; and
- work with wholesalers.

3. **Rita Sevier**, Deputy Director of Clinical Projects
617-210-5692, rsevier@ehs.state.ma.us

Area of consultation:

- 340B Best Practices

University of Massachusetts Medical School

Debra Chaison, 340B Project Manager
508-856-8149 Debra.Chaison@umassmed.edu

Areas of consultation:

- federal and state regulations and policy related to the 340B program; and
- pharmacy data and analysis.

Mass. League of Community Health Center (MLCHC)

George Stiles, 340B Consultant
617-426-2225, gstiles@massleague.org

APPENDIX C: CONTACT INFORMATION FOR 340B WHOLESALERS

Wholesaler contact information:

AmeriSource-Bergen
508-337-8750

Cardinal
1-800-388-9000

McKesson
1-800-842-1198

To the best of our knowledge, these are the current wholesalers participating in the 340B program in Massachusetts.

APPENDIX D: TYPES OF REPORTS PRODUCED BY A PHARMACY

Here are some reports that may be produced by a pharmacy. The pharmacy's ability to produce reports can vary by software and also by the amount of time needed to produce them. Work with your pharmacist to determine which reports you need for your health center.

Daily Reports

- Daily Log to keep track of
 - total prescriptions;
 - daily profit (cost of drugs vs. reimbursements); and
 - payer mix (retail, sample, UCC, MH, BC, etc).

Daily Drug Order Report

Based on preset reorder levels in drug file of computer, report is used when medication on hand drops below inventory level and drug will be reordered.

- Registered pharmacist (RPh.) will review this list and then generate order.
- Next day, RPh. can compare prices on this list to invoice price to check accuracy of drug pricing in the pharmacy computer system.

Daily Unpaid-Claims Report

- Shows any claim sent to insurer that was not paid for to any reason. RPh. can then review and take appropriate action.

Inventory Reports

- Can be run at any time to determine value of drugs in stock at pharmacy.

Clinician Reports

These reports show:

- prescribed drugs by clinician showing formulary compliance, use of generic vs. brand, or any other clinical issues or initiatives the health center might want to investigate;
- prescriptions filled at the 340B pharmacy; and
- drug price information (wide price differences within drugs of the same therapeutic class).

Patient Reports

Patient Compliance Reports are most useful to clinicians. These reports:

- identify patients that are not refilling prescriptions for maintenance medications when they should be. Each prescriber could get a report based on a specific time period that would show which patients did not receive refills due during that time period;
- note prescriptions filled but never picked up (such as when a prescriber calls the pharmacy with an oral prescription for a cholesterol-lowering drug, the patient never picks up prescription and continues to show elevated cholesterol levels); and
- can be tailored to meet the needs of the clinician. For example, a prescriber wants to see a list of his or her patients and their use of Albuterol inhalers. If it is noted that certain patients are using higher than expected amounts of Albuterol, the prescriber may want to add other maintenance medications to the patient's medication regimen.

Financial Reports

- Inventory reports (See Appendices E & F);
- Claim reconciliation reports to match payments received from a third party, such as Mass Health, with what was billed to that third party via on-line adjudication. There are some third parties that do not offer online adjudication such as the Free Care Pool. Reports would have to be generated showing the appropriate billing;
- Reports based on showing what amounts are outstanding from each third party;
- Reports generated from the POS system showing how much is owed to the state for sales tax collected from OTC items;
- Prescription logs generated with different types of criteria, such as drug, third party, or clinician, that would allow investigations into the profitability of these criteria. For example, you have three nasal steroid inhalers on your formulary. This report could show that one of these brings a much higher profit margin to the pharmacy and you may then want to encourage the use of this product over others; and
- Staffing reports showing prescriptions filled per hour per day over a period of time. For example, this report shows that a pharmacy typically fills many more prescriptions on a Friday afternoon as opposed to a Wednesday morning. The pharmacy could use this report for staffing purposes.

Patient Assistance Programs

- If a pharmacy is involved with dispensing prescriptions through PAPs, the pharmacy may want to run reports in anticipation of the next application process by the patient. If a patient has received a 90-day supply of a medication and needs a refill, it would not be wise to wait until the patient runs out of medication before the needed paperwork is sent to manufacturer because there may be a 30-day waiting period.

Over the Counter (OTC) items

- These contract items can be sold for cash over-the-counter to qualified patients without a prescription. Note that MassHealth covers some OTC drugs, and that a prescription is required for these drugs.
- In order to perform drug utilization reviews, track purchases and retain an audit trail by assigning each item a unique OTC number.
- Make sure that the transaction is not purporting to be a prescription, and is not stored with required prescription records.
- The information in the transaction would be the same as contained in a prescription file, except that there would be no directions or doctor assigned. OTC items billed to a third party would continue to require a prescription order from a physician.

APPENDIX E: IDEAS ON INVENTORY CONTROL AND REPORTING

1. The pharmacy should be able to keep a perpetual inventory (be able to report what's on hand at all times).
2. The pharmacy should be able to report by drug/NDC number, quantity, and cost of goods for inventory sold.
3. The health center can reconcile inventory using the method below. This method can be used monthly or as needed for drug specific audits. In a drug specific audit, the health center would go in and actually count the inventory on hand, and look at prescription records to make sure they correspond with dispensing reports.

Month 1

Initial Starting inventory (from invoice)

(+) purchases (from invoice)

(-) returns (from invoice)

(+) returns out of inventory not credited yet (from pharmacy)

 (-) cost of goods inventory dispensed (from pharmacy)

 (+) inventory returned to stock (from pharmacy)

(=) ending inventory

(compare to inventory reported by pharmacy)

Month 2

Ending inventory from last month

(+) purchases (from invoice)

(-) returns (from invoice)

(+) returns out of inventory not credited yet (from pharmacy)

 (-) cost of goods inventory dispensed (from pharmacy)

 (+) inventory returned to stock (from pharmacy)

(=) ending inventory

(compare to inventory reported by pharmacy)

Timing is critical when reconciling inventory by comparing invoice totals and pharmacy reports. You must make sure that you agree to include or exclude the last order placed prior to reports being run. The pharmacy could place the order, have it logged into their inventory, but not have received it yet. (This assumes that the last order of the month is invoiced for the last day of the month.)

Make sure the pharmacy runs their inventory report at the close of business. Ensure that a reporting system exists for returning unused items to stock (when the prescription is filled but the patient does not pick it up). Determine a period that is consistent so that after this predetermined number of days, unused items are credited to the insurance company and the inventory is returned to stock.

APPENDIX F: DEVELOPMENT OF STATEWIDE CHC PHARMACY & THERAPEUTICS (P&T) CENTER

MassHealth and the University of Massachusetts Medical School (UMMS) are sponsoring the development of a statewide P&T Committee for CHCs to participate in. The first meeting was in the fall of 2004. The resources they can provide are listed below.

Operational Support

- Plan meetings include developing agenda and reserving site.
- Provide all accommodations (such as, audiovisual materials and refreshments).
- Facilitate meetings including discussion and consensus.
- Assist with inviting specialists to meetings to provide expert opinion on relevant community health care issues, diseases, or medications.
- Prepare and distribute minutes of the meetings and other pertinent committee correspondences.
- Develop P&T Committee operating guidelines, including voting procedures for chair and chair-elect, selection of the committee, and length of appointment.

Clinical Support

- Provide expertise in formulary development.
- Develop clinical reviews of therapeutic classes.
- Provide drug monographs on new-to-market drugs.
- Assist with development of clinical guidelines.
- Develop guidelines on “best practices” relevant to community health centers.
- Develop educational materials, including prescriber letters.
- Provide literature searches.
- Assist with development of communication tools (newsletter, formulary, Web site).
- Provide experience and guidance for academic detailing.
- Clinical staff includes six pharmacists with doctorate of pharmacy degrees, four physician advisors, data analyst, and research coordinator.
- Determine level of involvement. Involvement may include taking the lead or providing assistance with these activities.